carital®

User’s guide

Optima*Bario*

KOHJ-H-03-EN5-1.0-15112022

Table of contents

1 Description of symbols used

1.1 Device and packaging symbols


Manufacturer


Do not use if the packaging is damaged or has been opened

Product code


Date of manufacture (yymmdd)


Store away from heat

Serial number

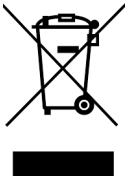

Double insulated device


See user's guide


Warning

Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR)


Type BF device


The device must be disposed of in accordance with EU directive 2002/96/EC (WEEE Directive).


Main fuse information

Permitted air humidity limits


Allowable air pressure limits

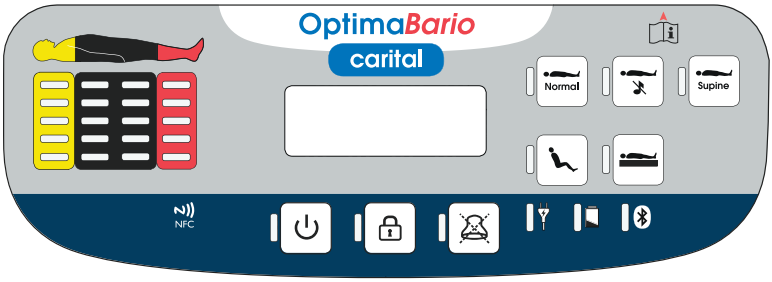

Keep protected from rain

IP22
Device IP class


Allowable temperature limits


Fragile, handle with care

1.2 Symbols on the controller's operating panel



General functions

Device standby button

Keypad lock

Acknowledgement of information signal

LED lights

Mains connected

Battery usage

Bluetooth connection established *(note: this feature is not yet implemented)*

LED lights indicating information signals and the adjustment of different adjustment regions

Operating modes

Normal operation

Silent operation

Supine operation

Sitting operation

Firm operation

Other

NFC tag location in device *(note: this feature is not yet implemented)*

2 Introduction

2.1 Intended purpose

Carital® Optima*Bario* is a mattress system for the prevention and treatment of pressure ulcers.

2.2 Operating environment and user profile

The Carital® Optima*Bario* mattress system is intended for both home use and healthcare environments (regular wards and intensive care).

The user can be a healthcare professional or a non-professional that has read the user's guide and understands the basic operating principle and use of the mattress system.

2.3 Target patients

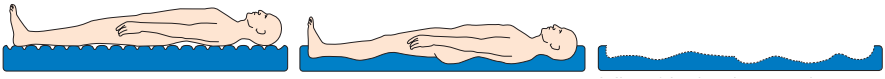
The Carital® Optima*Bario* mattress system has been designed for patients with very high or high risk of getting a pressure ulcer. The mattress system is intended for patients weighing 40–400 kg (cell width 90 cm) or 40–350 kg (cell width 85 cm).

2.4 Contraindications

The Carital® Optima*Bario* mattress system must not be used with patients with lower extremities amputated from the midline of the legs upwards.

2.5 System description

The Carital® Optima*Bario* mattress system has a double cell structure where the tunnel-shaped upper cells, lightly filled with air, adjust to the patient's body. The inner cells are interconnected, forming three separate adjustment regions (head, torso, feet). All cells respond to the weight, profile and position of the body, distributing the load evenly across all cells.



1. Initial situation
2. Adjusted mattress
3. The shape of an adjusted mattress without the patient.

The Carital® principle: Maximizes contact area, minimizes contact pressure and tissue deformation.

2.6 Products whose use is described in this guide

- Optima*Bario* controller and cells
- Medicase® and antistatic Medicase® hygiene cover
- Rehab and Comfort cover add-ons

This guide applies only to second-generation Carital® controllers. A second-generation controller can be identified with its serial number beginning with the PC identifier.

Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the Therapeutic Goods Administration (TGA).

Read this guide carefully before starting to use the mattress system. Persons who have not read this user's guide or cannot understand its content may not operate the mattress system independently.

Keep this guide.

2.7 Warnings

- This guide applies only to second-generation Carital® controllers. A second-generation controller can be identified with its serial number beginning with the PC identifier.
- Only healthcare professionals can assess the need for and suitability of a mattress system in the treatment situation.
- Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the Therapeutic Goods Administration (TGA).
- If you have any questions regarding the commissioning, use or maintenance of the mattress system or if you notice that the device works in an unanticipated way or a way not described in this guide, contact the mattress system's reseller.
- Contact the mattress system's reseller if any part of the mattress system is damaged or works in an unusual way. Do not attempt to repair damage before contacting the reseller.
- Do not use the device if the configuration is incomplete or any of its components is broken, worn or contaminated. Worn, missing and broken parts must be replaced and contaminated once cleaned.
- Do not modify the mattress system and do not connect the mattress system to other devices without the manufacturer's permission. Unauthorised modifications and connections may pose a danger to the user of the mattress system.

- The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

- Use only original Carital® spare parts and accessories.

- The temperature of the controller may have decreased or increased during transport beyond the limits of the allowable operating temperatures. Do not use the controller before it has been at room temperature (~ +20°C) for at least two hours. This time is required for all components of the controller to reach the normal recommended operating temperature of +10 – +35°C.

- Ensure that the settings of the device do not change unintentionally, for example because of children or pets. If necessary and the operating environment poses a risk of inadvertent changes of control operating modes, use the keypad lock in the controller.

- A twisted air tube or controller power cable around the neck or head may result in suffocation. Make sure that the air tubes and the controller's power cable cannot twist around the head or neck.

- Place the controller's power cable in such a way that it cannot be clamped in any situation, for example by the sides or folding parts of the bed.

- The power cable of the controller must always be plugged into the outlet, excluding short patient transports or similar situations.

- To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

- Always place the controller in such a way that it can easily be disconnected from the mains. Ensure that the control panel and connectors of the controller are always accessible.

- If the Sixtube connector of the air tube system is disconnected from the controller, the cells will deflate.

- Never use the mattress system without a cover on the cells.

- Do not use extra bed sheets, pillows or heavy positioning pillows on the mattress system.

- Before placing the patient on the mattress, start the device as described in section 5.1, and allow the mattress system to adjust to *Normal* operation successfully, so that all green LEDs are lit in the centre of the LED light bar.

- The dimensions of the mattress should always fit to the size of the patient, such that the pressure in all the adjustment sections are optimally placed to be regulated by the controller in correspondence to the patient's body parts.

- If side rails are used with the Carital® mattress system, make sure that the height of the side rails is at least 350mm from the bed base covering at least 50% of the length of the mattress.

- The support surface should fit the bed so that it does not extend over the edges of the bed or that no gap is formed between the support surface and the edges of the bed.
- With electrically adjustable beds, the suspension straps must be secured to the moving back part of the lying surface, not to the fixed part of the bed body.
- Do not place a power cable in the conduit if you believe the power cable may be clamped by the sides or folding parts of the bed.
- When using Rehab add-on for the cover, make sure the patient is always lying on the cells, not on the side supports.
- If *Sitting* operation is used for more than 60 minutes at a time, the patient is subject to an elevated risk of pressure ulcers.
- When the cells are hardened, their pressure reduction capacity is reduced.
- *Supine* operation is used only for the treatment of immobile patients on horizontal position, lying on their backs. Selecting *Supine* operation in other treatment positions will increase the risk of pressure ulcers. Make sure the patient is lying horizontally on their back when selecting this function.
- The controller is only able to detect defective inner cells according to chapter 6.3. The defective upper cells must be identified by the user according to the instructions stated in chapter 7.2.3.
- When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells. Do not use *Firm* operation when resuscitating.
- Do not immerse the controller in liquid.
- Do not cover the controller while in operation.
- Be sure to put the quick guide caddy back in place after examination.
- Do not lift the mattress by holding the cells or the cover.
- Sharp objects may puncture the cells.
- If the cover or cells are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the cover or the cells. Clean the cover and/or cells immediately if exposed to urea.
- Do not clean the plastic parts of the mattress system using solvents, phenols or clean alcohols.
- Ensure that the cover is entirely dry before commissioning it.
- Do not wash the side supports made of foam plastic.

- If the mattress is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the mattress system is used by a prominently sweating or mobile patient, the estimated life cycle of the cover and the cells may be shortened.

- Do not store anything on top of the mattress system.

- Do not place sharp or heavy objects on or near the mattress system.

- Keep the controller away from heat sources.

- Avoid using the controller in the proximity of other electric devices or in a stacked configuration, as this may interfere with the controller's operation. If the above use is necessary, ensure the normal operation of the controller by monitoring it.

- Using accessories, transformers or cables other than those specified by the manufacturer or supplied with the device may result in elevated electromagnetic emissions or reduced electromagnetic immunity and have adverse effect on the performance of the controller for its intended purpose.

- The distance of portable devices communicating using radio frequencies (including antenna cables and external antennas) to the controller and its cables should be at least 30 cm so as to ensure the performance specified in the technical files of the controller.

- The controller is intended for long-term use. However, it contains components that may break if the product is dropped or subjected to impact or vibration exceeding design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

- The batteries may only be replaced by Carital® service. Incorrect battery replacement may result in a situation where the device will not work correctly.

- Contaminated components must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.

- If the controller has encountered a significant mechanical strain (dropped, hard collision or similar), check the mechanical condition of the control port's connection gates and ensure that the seals between the operator panel/frame and the connection port/base plastic parts and the body are in place. If you notice any damage to the device, contact Carital® service.

- Maintenance and repair must always be carried out by Carital® service. The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

- If the mattress system behaves contrary to the functions and situations described in this user's guide, disconnect the air tubing from the cell's tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

- The mattress system must always be serviced according to the service programme described in this guide. A device that has not been serviced in accordance with the service programme must not be used but must be sent to Carital® service, instead. The user is responsible for any and all consequences resulting from neglecting service.

- Scheduled maintenance may only be carried out by Carital® service.

3 Covers

This section presents the cover types available for the Carital® Optima*Bario* mattress system as well as how to take off and put on the cover.

3.1 Medicase® hygiene cover

The Medicase® hygiene cover protects the mattress system's cells from liquids and body fluids. The surface of the cover is polyurethane and the lower layer is polyester. The cover can be removed using zippers on three sides.

There is a power cable conduit on the edge of the cover with power cable pre-installed. The air tubes of the cells are routed out at the left corner of the cover at the foot end. The integrated conduit prevents the power cable from being clamped by the sides of the bed or run over by its wheels when moving the bed.

Do not place a power cable in the conduit if you believe the power cable may be clamped by the sides or folding parts of the bed.

3.2 Antistatic Medicase® hygiene cover

The antistatic Medicase® hygiene cover protects the mattress' cells from liquid ingress and prevents the build-up of static charge (surface resistance ≤ 105 Ω). The antistatic cover is intended specifically for environments where the build-up of static charge may pose a safety risk.

The surface of the cover is polyurethane and the lower layer is polyamide. The cover can be removed using zippers on three sides.

There is a power cable conduit on the edge of the cover with power cable pre-installed. The air tubes of the cells are routed out at the left corner of the cover at the foot end. The integrated conduit prevents the power cable from being clamped by the sides of the bed or run over by its wheels when moving the bed.

Do not place a power cable in the conduit if you believe the power cable may be clamped by the sides or folding parts of the bed.

3.3 Rehab add-on for the cover

All covers are available with integrated Rehab side bars. The side support bars improve the support of the support surface's edge, promoting the patient's independent getting up from the bed and sitting down on it.

- There are dedicated hygiene covers for the side bars.
- Side bars are available in one-side and two-side configurations. In the one-side configuration, the side of the bar can be changed as necessary.
- Make sure that the side support bar is correctly positioned in such a way that its wedge at the foot end has the sloped part up.

Wedged side support bar of the Rehab add-on.

When using Rehab add-on for the cover, make sure the patient is always lying on the cells, not on the side supports.

3.4 Comfort add-on for the Medicase® hygiene cover

The Comfort cover is the Medicase® hygiene cover plus a detachable cotton top. The top can be detached by undoing two zippers.

The Comfort option is not available for the antistatic Medicase® hygiene cover.

3.5 Taking off the cover

NOTE!
The pictures show the Optima cell system. Optima*Bario* cover is black or blue/black but otherwise identical in design to the cover shown in the pictures.

1. *Remove the mattress from the controller by disconnecting the air tube system and power cable. Disconnect the power cable from the electrical outlet.*

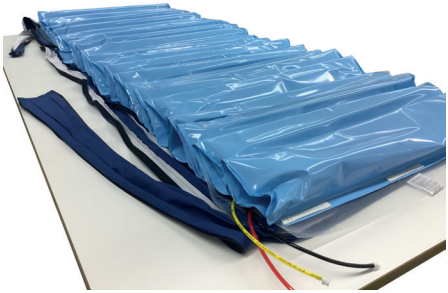
2. *Start by pulling down the zipper on the tube sleeve.*

3. *Open the zipper fully to expose the air tube system and power cable.*

4. *Pass the power cable and plug out of the tube sleeve.*

5. *Open the mattress zipper from the end until the air tube connectors are visible.*

6. *If necessary, disconnect the air tubing from the cell's tube system. Pass the air tubing through its hole.*



7. Open the mattress zipper fully.

8. Pass the cell's suspension straps out from their holes.

3.6 Putting on the cover

1. Place the cell over the cover. Ensure that the label in the foot section indicating the direction to put on the cover is faced correctly.

2. If you notice any protruding inner cells, evenly pull them inside the upper cells.

3. Check that the necessary accessories are readily available: power cable, air tubes, suspension straps (2) and side support bars (only covers with the Rehab add-on).

4. To secure the strap, pass it through the first cell fastener adapter.

5. *Pass the strap through the lock, adjust the strap to be uniform in length and close the lock.*

6. *Pass the strap through the hole in the cover. Repeat for the other strap.*

7. *Close the cover zipper and pass the cell air tubes out of their hole.* ***Note: If the cover includes the Rehab add-on, place the side support bars as instructed in section 3.3.***

8. *Pass the power cable plug from the hole in the tube sleeve. Attach the air tubing to the cell's air tube system.*

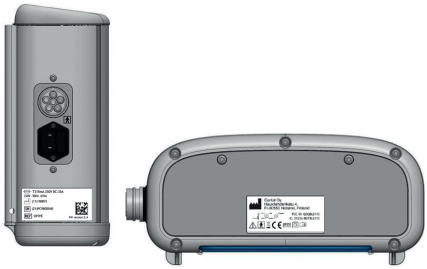
9. *Close the zipper on the tube sleeve.*

4 Commissioning

4.1 Components of the mattress system

Controller

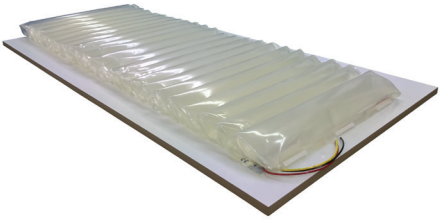
Controller



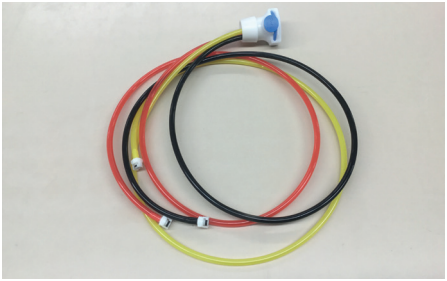
Type plate stickers on the side and at the bottom of the controller contain the device identification information.

The lockable power cable (5 m). The power cable is delivered pre-installed in its designated conduit in the cover.

Cells



Cells without cover. The cells are delivered with the cover on. The size and serial number of the cells are marked on the bottom mat of the cells close to the air tube outlet.



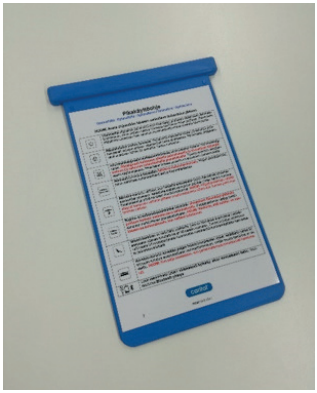
Air tube system between the controller and cells, including connectors

Cover

The cover is delivered pre-installed on the cells. The cover is equipped with a label that indicates the size, type, time of manufacture, manufacturer data, and washing and cleaning instructions for the cover.

Other

The controller has an integrated two-sided quick guide that describes the functions of the device and provides an example of troubleshooting.



The double-sided quick guide is found on the back of the controller and is released for viewing by raising it upwards.

Be sure to put the quick guide caddy back in place after examination.

The delivery also includes this long-form user's guide.

If the delivery set is damaged or incomplete, do not commission the device. Immediately contact the mattress system's reseller.

The temperature of the controller may have decreased or increased during transport beyond the limits of the allowable operating temperatures. Do not use the controller before it has been at room temperature (~ +20°C) for at least two hours. This time is required for all components of the controller to reach the normal recommended operating temperature of +10°C – +35°C.

4.2 Connecting the mattress system to the bed

The Optima*Bario* mattress system is intended for use in place of a regular support surface. The mattress system can be installed in all standard beds but the base of the bed must be as flat as possible. If the base is uneven or there are large gaps in the lying surface, an extra bottom support foam (optional accessory) can be used inside the cover underneath the cells.

The support surface should fit the bed so that it does not extend over the edges of the bed or that no gap is formed between the support surface and the edges of the bed.

If side rails are used with the Carital® mattress system, make sure that the height of the side rails is at least 350 mm from the bed base covering at least 50% of the length of the mattress.

The mattress system can also be used with electrically controlled beds with adjustable back and leg parts. Any sliding of the mattress may be prevented by attaching the cells to the bed using suspension straps through the cover. The suspension straps must be attached to the mobile, rising/lowering back part of the bed's lying surface.

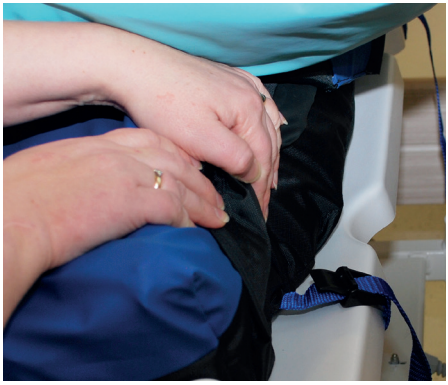
Attaching the straps

1. Pass the strap ends through the holes on the back part of the bed.

2. Pull the strap through the lock, tighten securely and press the lock toward the strap to lock.

3. Repeat on the other side.

Undoing the straps



1. Lift the lock up.

2. Pull the strap through the lock.

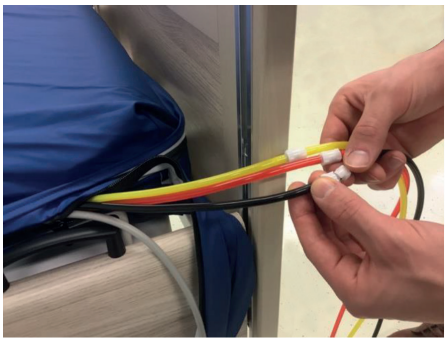
With electrically adjustable beds, the suspension straps must be secured to the moving back part of the lying surface, not to the fixed part of the bed body.

Do not use extra bed sheets, pillows or heavy positioning pillows on the mattress.

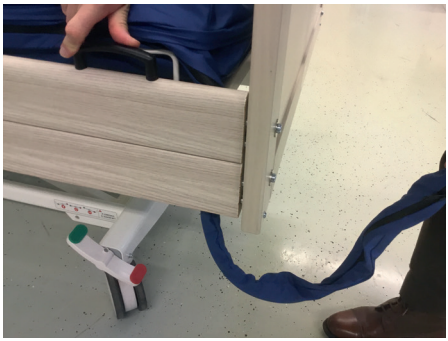
If side rails are used with the Carital® mattress system, make sure that the height of the side rails is at least 350 mm from the bed base-covering at least 50% of the length of the mattress.

4.3 Commissioning the controller

1. *Suspend the controller at the end of the bed in as central position as possible.*

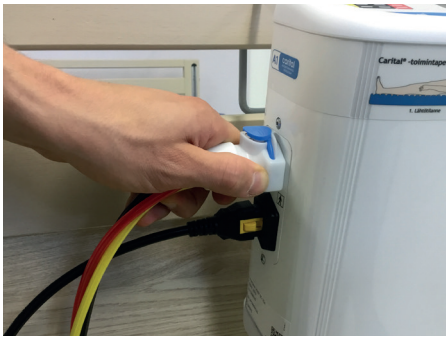


2. *To connect the three colour-coded tubes of the air tube system to their counterpieces, push and turn them clockwise.*

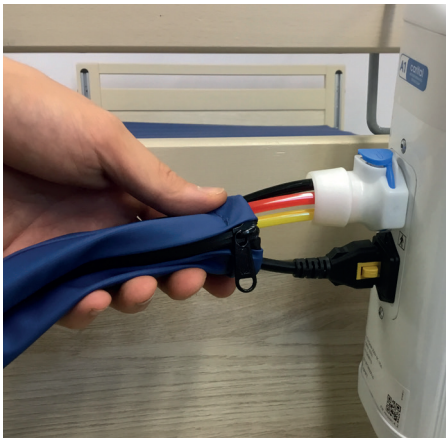


3. *Close the zipper of the tube sleeve and make sure that the tube sleeve is as secure as possible in relation to the bed structure.*

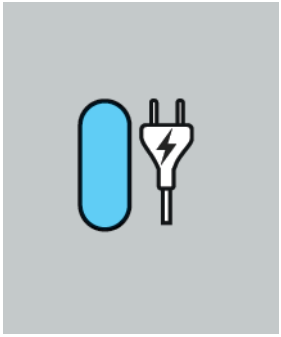
4. *Connect the power cable to the mains connector of the controller.*



5. *Connect the Sixtube connector to the controller with the blue release button facing up and make sure the connector snaps when locking into place.*



6. *Pass the protective tube sleeve as far up as possible towards the controller. Close the zipper.*



7. *Plug the power cable into an electrical outlet. The LED indicating a connected mains cable lights up.*

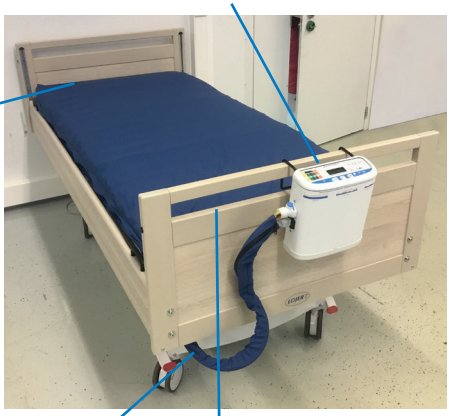
4.4 Lifting the controller

As a general rule, lift and handle the controller using two hands on both sides of the body or according to the instructions with the attached suspender.

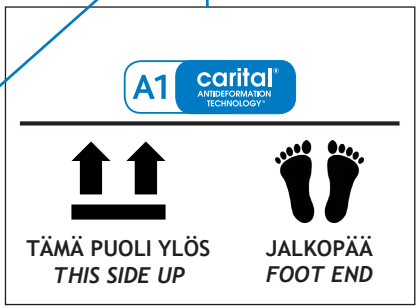
4.5 Things to check before use

When attaching the mattress system to the bed structure, ensure that both suspension straps are attached and tightened according to instructions.

Ensure that the controller has been suspended in as central position as possible at the foot end of the bed. Ensure that there is sufficient space around the controller for operation and unobstructed disconnection.



Make sure the tube sleeve has been routed in the bed structure in such a way that it cannot be clamped by the folding parts of the bed.



Ensure that the label indicating the correct direction of installation of the mattress system is located at the foot end and facing upward.

To guarantee fault-free operation of the controller, the power cable must always be connected to the mains, with the exception of short patient transports and power outages.

Always place the controller in such a way that it can easily be disconnected from the mains. Ensure that the control panel and connectors of the controller are always accessible.

5 Operation

5.1 Turning on the controller and activating Normal operation

Normal operation is intended for patients with very high or high risk of pressure ulcer who may lie on their back or side.

Whenever the controller is turned on, it will start in *Normal* operation. There is no time limit for this function.

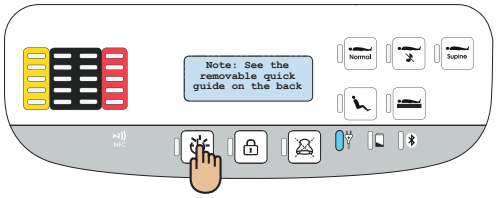
Only healthcare professionals can assess the need for and suitability of a mattress system in the treatment situation.

Before placing the patient on the mattress, start the device as described in section 5.1, and allow the mattress system to adjust to *Normal* function successfully, so that all green LEDs are lit in the centre of the LED light bar.

The dimensions of the mattress should always fit to the size of the patient, such that the pressure in all the adjustment sections are optimally placed to be regulated by the controller in correspondence to the patient's body parts.

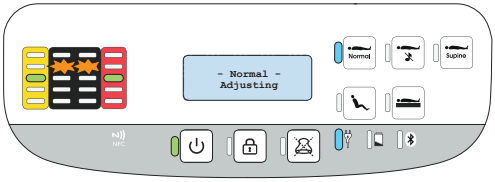
Make sure that the controller is connected according to the instructions in the section 4.3 Commissioning the controller, and check the required things before use.

To turn on the controller, press down the device standby button briefly. The device prompts you to consult the quick guide that can be found on the removable tray behind the device.



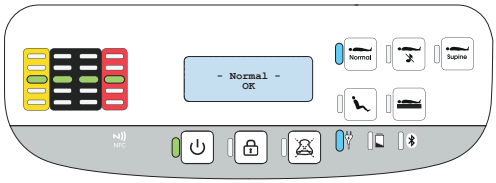
The mattress system is set to *Normal* operation.

The device will first adjust the foot region, then the head and finally the torso. If *Normal* operation is selected later after startup, the device will first adjust the torso, followed by the foot region and the head.

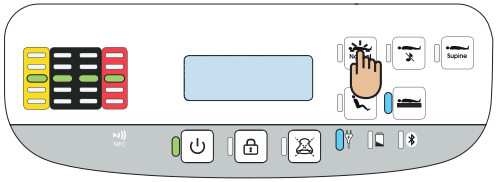


The LED light bars for the cells will rise up or fall down with the adjustment of the cells.

When the mattress system has successfully activated *Normal* operation, green LED indicators will light up in the centre of the LED light bar.



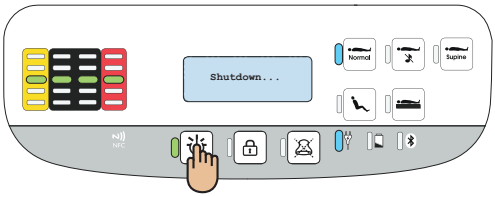
To later restore *Normal* operation of the controller from another mode, press the *Normal* operation button as shown in the figure.



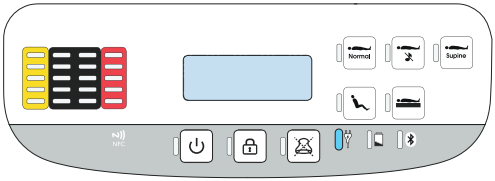
5.2 Turning off the controller

To turn off the controller in any operating mode, press the device's standby button.

The controller can be turned off in any operating mode by pressing the device's standby button.



The device remains connected to the mains and the power connection LED will stay lit until the device is disconnected from the mains.



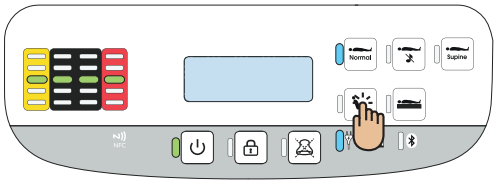
5.3 Sitting operation

Sitting operation is intended for patients in a sitting position with the back part of the bed elevated at an angle of more than 30 degrees.

Sitting operation can be in use for 60 minutes in one go, after which the visual information signal of the controller will alert the care personnel to the increased risk for pressure ulcers. For more information on the information signal, refer to section 6 of this guide.

If *Sitting* operation is used for more than 60 minutes at a time, the patient is subject to an elevated risk of pressure ulcers.

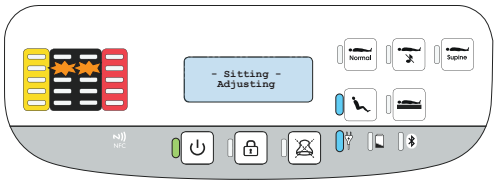
With the device in operation, press the *Sitting* operation button to activate the function.



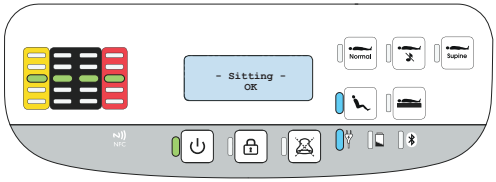
The device will switch to *Sitting* operation.

The device will first adjust the torso, then the foot region and finally the head.

The *Sitting* operation LED is lit and the cell LEDs will move up or down.



The device has activated *Sitting* operation. The *Sitting* operation LED is lit and the cell LEDs are lit on the centre row.



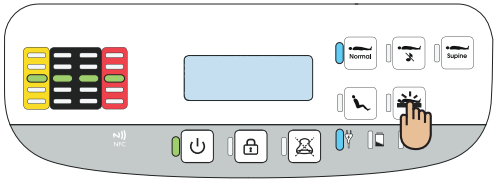
5.4 Firm operation

Firm operation hardens the entire mattress system for patient care. The device will automatically resume *Normal* operation 30 minutes after this function is selected if nothing else is selected.

When the cells are hardened, their pressure reduction capacity is reduced.

With the device in operation, press the *Firm* operation button to activate the function.

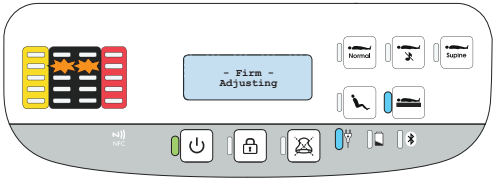
The LED on the function lights up.



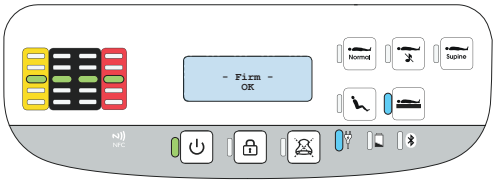
The device activates *Firm* operation.

The device will first adjust the torso, then the foot region and finally the head.

The cell LEDs will go up.



The device has activated *Firm* operation. The *Firm* operation LED is lit and the cell LEDs are lit on the centre row.



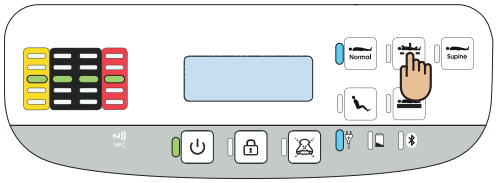
5.5 Silent operation

The Silent operation can be selected in a situation where you want to minimize the operation of your device's control cycles and pump function, for example during night time when the patient is asleep.

The controller adjusts the cell pressures to *Normal* operation pre-set values and then retains them unchanged. This allows the controller to monitor the pressure in the torso cells. If the pressure values of the torso cells are continuously outside the permissible limit values for 45 minutes, the device will start adjusting all the cell parts again, starting from the torso cells.

Eight (8) hours after selecting the *Silent* operation, the device automatically returns to *Normal* operation.

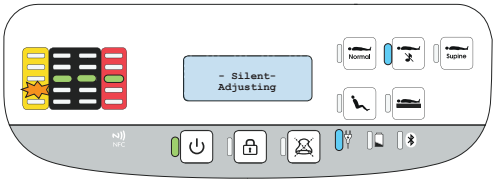
With the device in operation, press the *Silent* operation button to activate the function.



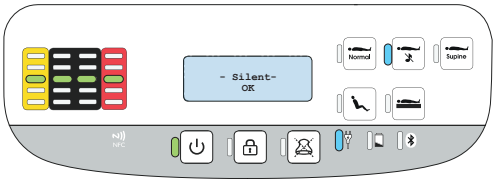
The device activates *Silent* operation.

The device will first adjust the torso, then the foot region and finally the head.

The operation LED is lit and the cell LEDs will go up or down.



The device has activated *Silent* operation. The operation LED is lit and the cell LEDs are lit on the centre row.



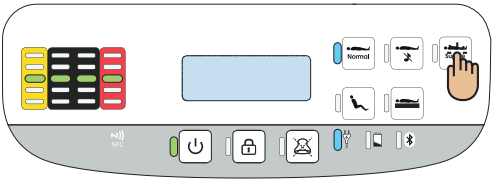
5.6 Supine operation

Supine operation is used only for the treatment of immobile patients on horizontal position, lying on their backs. The mattress system adjusts to the lowest possible pressure setting, which achieves the best possible therapeutic level.

Supine operation is used only for the treatment of immobile patients on horizontal position, lying on their backs. Selecting *Supine* operation in other treatment positions will increase the risk of pressure ulcers. Make sure the patient is lying horizontally on their back when selecting this function.

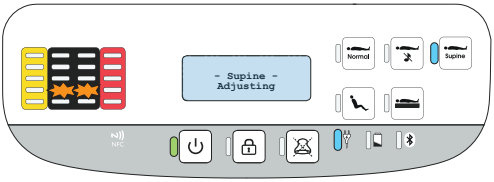
With the device in operation, press the *Supine* operation button to activate the function.

The device activates *Supine* operation.

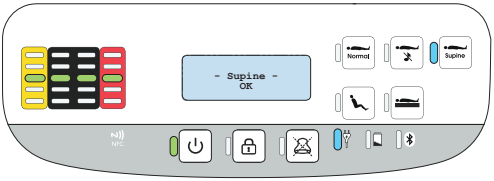


The device will first adjust the torso, then the foot region and finally the head.

The operation LED is lit and the cell LEDs will go down.



The device has activated *Supine* operation. The operation LED is lit and the cell LEDs are lit on the centre row.

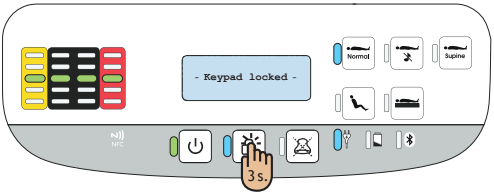


5.7 Keypad lock

The controller's keypad can be locked if deemed necessary considering the conditions of the operating environment.

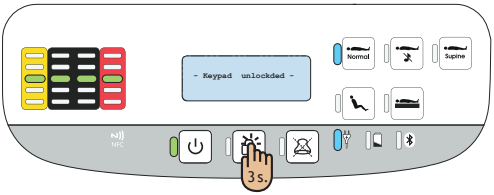
To lock the keys of the controller, press and hold down the keypad lock button for three (3) seconds while the device is running.

Keypad locking is indicated on the device screen. The LED on the keypad lock turns on.



To deactivate the keypad lock, press and hold down the keypad lock button for three (3) seconds until the display reads "Keypad unlocked."

The LED on the keypad lock turns off.



5.8 Operating the controller using battery power

The controller must be connected to the mains by a power cable whenever possible. In exceptional cases, the controller can be operated for a short time using battery power. Allow the controller to be running and connected to the cells during transport. The mattress system will then run on the internal battery of the device.

Under normal operating conditions, a fully charged battery will suffice for at least 30 minutes of continuous pumping of the cells. The battery will charge from empty to full in approximately 12 hours.

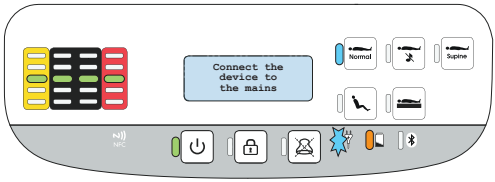
When transporting patients: Disconnect the device's power cable from the mains and make sure that the cable cannot be run over by the bed wheels, for instance, during transport. Once the patient transport is finished, connect the controller back to the mains by connecting the power cable to an electrical outlet. The cells will not deflate during transport.

The controller must be connected to the mains whenever possible. In exceptional cases, the controller can be operated for a short time using battery power.

If the Sixtube connector of the air tube system is disconnected from the controller, the cells will deflate.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

If the device is disconnected from the mains while running, it will automatically continue running powered by its internal battery.



The device indicates the battery usage by flashing the LED light on the network interface and by lighting up the battery usage LED. In addition, the device notifies you of the disconnected mains cable by beeping five times and prompts you to connect the device to mains.

The device reminds of connecting to the mains with a simple beep, if the function keys of the device are pressed during battery usage.

For instructions on what to do if battery charge falls below the level required for normal operation, see section 6.9 (Information signals - Battery charge falls low).

5.9 Resuscitation situations

WHEN RESUSCITATING:
Turn off the device from the standby button and begin CPR immediately without deflating the cells.

When resuscitating, turn off the device from the standby button and start CPR immediately without deflating the cells. Do not use *Firm* operation when resuscitating.

5.10 Fault situations

The identified fault situations of the mattress system and detecting them is described in the sections 6 and 7.2.

If the mattress system behaves contrary to the functions and situations described in this user's manual, disconnect the air tubing from the cell's tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

5.11 Function during power outage

Below you will find instructions for operating the mattress system during a power outage or during a higher risk of power outages in the operating environment.

1) Before a power outage:

- During normal circumstances the mattress system controller must always be connected to the mains for the internal battery to maintain as high charge as possible during a potential power outage. The battery will charge from empty to full in approximately 12 hours.
- As far as possible, prepare for supporting the operating environment with an emergency power supply.

To maintain the battery's performance, keep the controller continuously connected to the mains for 12 hours at least every three (3) months.

2) During a power outage:

- When the mains is cut off, the mattress system switches to running on the internal battery in accordance with chapter 5.8. The air cells will be controlled normally with the chosen function until the battery charge falls low in accordance with chapter 6.9. Under normal operating conditions, a fully charged battery will suffice for at least 30 minutes of continuous pumping of the cells.
- If the outage lasts for longer than the battery charge, the controller will shut down in accordance with chapter 6.9. When the controller shuts down, the pressure controlled by the mattress system will remain in the closed air system cells.
- Do not disconnect the Sixtube connector from the controller, as it will deflate the air cells.

If the Sixtube connector of the air tube system is disconnected from the controller, the cells will deflate.

3) After a power outage:

- If the charge of the mattress system battery has been sufficient during the power outage, the controller will continue functioning normally without further action when the power is restored.
- If the controller has shut down because of low battery (see 6.9), the controller must be restarted in accordance with chapter 5.1 when the power is restored and set to the desired function.
- In both cases mentioned above, you must ensure that after the outage the controller is continuously connected to the mains for 12 hours to regain a full battery.

6 Information signals

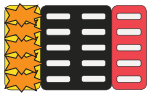
If the controller detects a failure or wishes to inform the user, it will provide audible and visual indication using the display, information signal LED and LED bars. This section describes how the information signals must be interpreted and what action they require from users.

Below is a list of information signals in the LED display and references to more detailed troubleshooting guides:

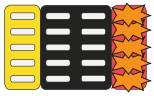
6.1 Pressure sensor function error

6.2 Elevated pressure ulcer risk (sitting operation)

6.3 Check the air tubes (leak in tube or inner cells)
- potential leak in the torso section



6.3 Check the air tubes (leak in tube or inner cells)
- potential leak in the head section



6.3 Check the air tubes (leak in tube or inner cells)
- potential leak in the foot section

6.4 Pressure target value invalid

6.5 SD card operating error

6.6 Scheduled maintenance notices

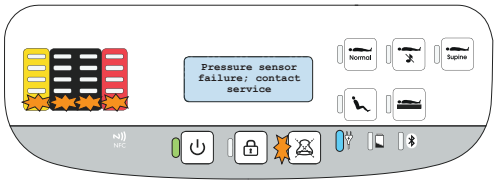
6.8 Battery operating error

6.9 Battery charge falls low

6.10 Device internal error

6.1 Pressure sensor function error

The LED row will light up as shown in the figure. The LED for the information signal reset button blinks and the display indicates failure.

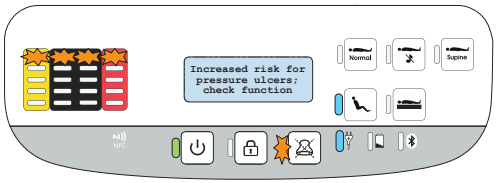


To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.2 Elevated pressure ulcer risk (sitting operation)

If the *Sitting* operation is continuously switched on for more than 60 minutes, a reminder of the elevated pressure ulcer risk is given.



The LED row will light up as shown in the figure.

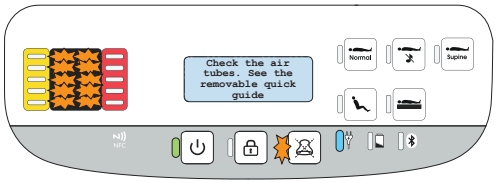
The LED for the information signal reset button blinks and the display reads, “Increased risk for pressure ulcers; check function”.

Once the information signal acknowledgement button is pressed, the visual signal stops flashing. Press and hold down the button for three seconds to acknowledge the entire signal and have the device start operation from the beginning with a new timer.

The information signal can also be acknowledged by selecting another function from the controller.

6.3 Check the air tubes (leak in tube or inner cells)

The information signal reset button blinks and the display reads, “Check the air tubes. See the removable quick guide”.



This information signal is displayed if the device does not achieve the desired function of the active operation within 45 minutes. This may be due to a disconnected tube or a leak in the inner cell or tube system, among other causes.

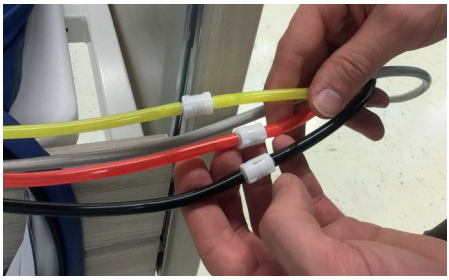
The controller is only able to detect defective inner cells according to chapter 6.3. The defective upper cells must be identified by the user according to the instructions stated in chapter 7.2.3.

The LED display is lit for that area of operation where the controller has failed to achieve the target pressure value for the function. In this example, the issue has been detected in the torso section of the cell.

Perform the following tasks:

First check whether the Sixtube connector connected to the controller is locked in place and whether its attached tubes are in their holders.

Open the tube sleeve until the tube connectors are revealed: check whether the tubes between the cells and controller are connected to their connectors. Also check that the colours match (for example, black on black). Check whether there is any clearly visible damage to the cells or leaks in them.



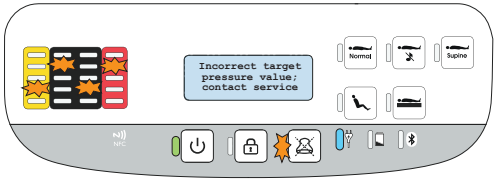
If you notice any loose tubes, connect them to each other as appropriate. Close the tube sleeve.

When you have checked the above, acknowledge the information signal by pressing and holding down the information signal reset button for three seconds.

If the information signal persists or you detect a leak in the mattress system, contact Carital® service.

6.4 Pressure target value invalid

The LED row will light up as shown in the figure and the display will read, “Incorrect target pressure value, contact service”.



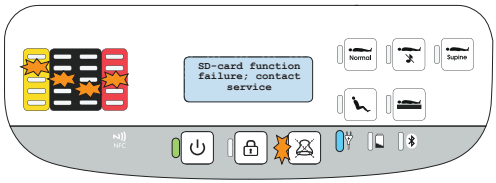
To acknowledge the failure indication signal, press the information signal reset button.

Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation. The audible information signal will start again if the device is restarted.

Immediately contact Carital® service.

6.5 SD card operating error

The LED row will light up as shown in the figure and the display will read, “SD card function failure; contact service”.



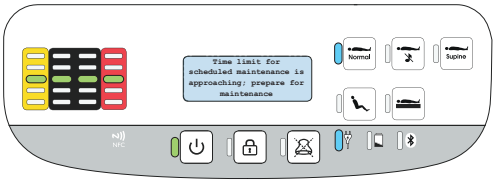
To acknowledge the failure indication signal, press the information signal reset button.

Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.6 Scheduled maintenance notices

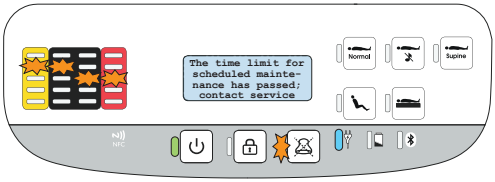
The display will read, “Time limit for scheduled maintenance is approaching; prepare for maintenance”.



Prepare to send the controller in for scheduled maintenance after one (1) month.

After this, the device will display a reminder for 5 seconds whenever a function button is pressed or the device is turned on.

The LED row will light up as shown in the figure and the display will read, “The time limit for scheduled maintenance has passed; contact service”.



Immediately contact Carital® service and send the controller in for scheduled maintenance.

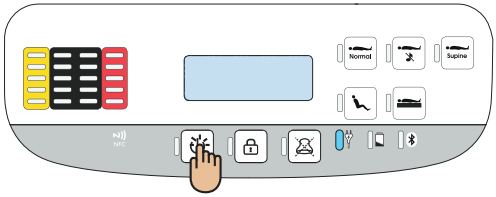
To acknowledge the indication signal, press the information signal reset button. The LED will stop blinking and remain on continuously. Press and hold down the information signal reset button for three (3) seconds to turn off the LED and remove the visual signal from the display.

After this, the device will display a reminder for 5 seconds whenever a function button is pressed and provide a new information signal when the device is turned on.

6.7 Electromagnetic interference and display information fault situations

1)
If the device display is exposed to an unexpected electrostatic discharge, the display information and letters may be shown in an illogical way.

Turn the controller off and on with the standby button shown in the figure. The device will resume *Normal* operation after restarting.



If the device does not resume *Normal* operation, discontinue using the device and **contact Carital® service**.

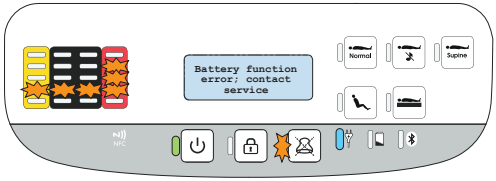
2)
If the device is exposed to significant electromagnetic interference in excess of the thresholds specified in Appendix 1, a situation may result where the device's mode of operation will randomly change without user action.

Move the device further from the source of the electromagnetic interference to eliminate the interference and restart the device if necessary.

If the device does not resume *Normal* operation, discontinue using the device and **contact Carital® service**.

6.8 Battery operating error

If the battery temperature of the device rises too high, and the charging is interrupted or the battery does not charge as expected and the charger times out, the device will report a malfunction with the information signal.



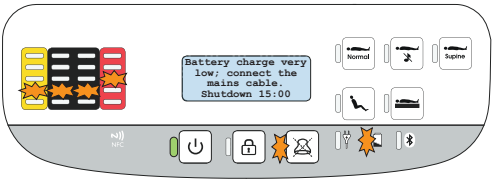
The LED row will light up as shown in the figure. The LED for the information signal reset button blinks and the display indicates operating error.

To acknowledge the failure indication signal, press the information signal reset button. Only the audible part of the information signal is acknowledged. The visual information signals will remain on and the device will not resume previous operation.

Immediately contact Carital® service.

6.9 Battery charge falls low

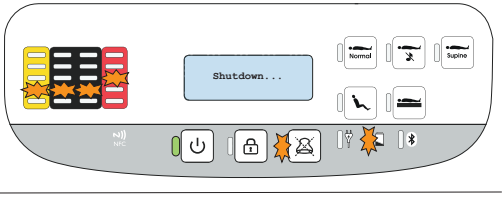
When the charge of the internal battery falls to a very low level (7.2V–7.0V), the controller will provide an information signal.



Despite acknowledging the indication signal, the visual signals will remain on and the adjustment of the mattress system will cease until the device is connected back to the mains.

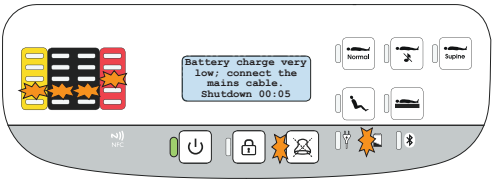
The 15-minute timer for the self-shutdown of the controller will start running. The device will indicate the decreasing time on the display.

After 15 minutes, the device will turn off completely and indicate this with a sound and on the device screen.



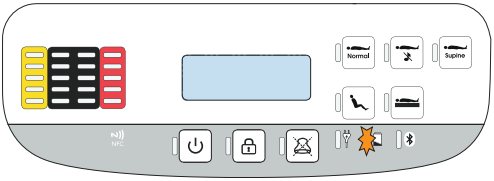
When the device is connected back to the mains, restart it by pressing the standby button.

If the device shuts down after the counter process, and it is restarted, the device turns off after 5 seconds from booting.



The battery indicator flashes for 20 seconds after the restart attempt begins.

If the internal charge of the battery reaches the critical low point (< 7.0V), the device turns off immediately and flashes the battery light for 20 seconds.



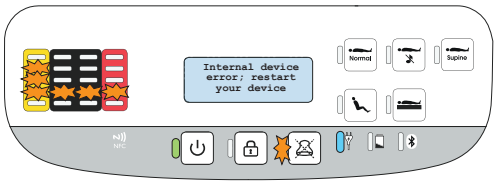
Restart attempts from now on will only generate the battery indicator light (20 sec.) until the device is connected to mains again.

NOTE:
When the levels of very low or critical voltage are reached, the battery operation cannot be resumed, but the device must be plugged into the mains. Normal battery usage is possible once the device has been charging for approx. 5 to 6 hours (depending on the condition of the battery). If the device is disconnected from the mains before an adequate charge level has been reached, the device will shut down itself after 5 seconds after booting.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

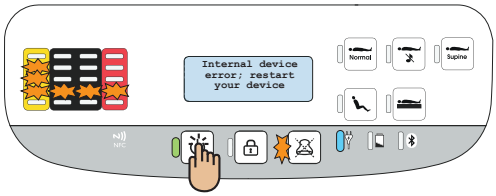
6.10 Device internal error

The LED row lights up as shown in the figure and the display shows "Internal device error; restart your device".



The indication signal of this one-time malfunction failure state can be acknowledged by pressing the acknowledgement button of the indication signal. The indication signal is acknowledged only for sound, visual information signals remain on.

The device will no longer return to the previous operation and will require a restart. Press the standby button to restart the device.



If the indication signal is not removed after restarting, contact Carital® service immediately.

NOTE:
Check your Carital® service contact information on the last page of the user's guide.

If the controller has encountered a significant mechanical strain (dropped, hard collision or similar), check the mechanical condition of the control port's connection gates and ensure that the seals between the operator panel/frame and the connection port/base plastic parts and the body are in place. If you notice any damage to the device, contact Carital® service.

Do not use the device if the configuration is incomplete or any of its components is broken, worn or contaminated. Worn, missing and broken parts must be replaced and contaminated ones cleaned.

Maintenance and repair must always be carried out by Carital® service. The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than Carital® service.

If the mattress system behaves contrary to the functions and situations described in this user's guide, disconnect the air tubing from the cell's tube system and the power cable from the controller, turn off the controller, and contact Carital® service.

The mattress system must always be serviced according to the service programme described in this guide. A device that has not been serviced in accordance with the service programme must not be used but must be sent to Carital® service, instead. The user is responsible for any and all consequences resulting from neglecting service.

Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the Therapeutic Goods Administration (TGA).

7 Maintenance and storage

7.1 Cleaning

The mattress system must be cleaned in accordance with these instructions whenever

- there is suspicion that any part of the mattress system is contaminated
- there is visible dirt or secretions on the cover
- the patient using the mattress system changes
- before maintenance and repair

Do not clean the plastic parts of the mattress system using solvents, phenols or clean alcohols.

If the cover or cells are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the cover or the cells. Clean the cover and/or cells immediately if exposed to urea.

7.1.1 Controller and tube system

Disinfect by wiping using regular cleaning and disinfection agents (including ethanol solutions 60–80%, chlorine solutions max. 1,000 ppm).

Dry at room temperature.

Do not immerse the controller in liquid.

7.1.2 Cells

Disinfect by wiping using regular cleaning and disinfection agents (including ethanol solutions 60–80%, chlorine solutions max. 1,000ppm).

The cells can also be disinfected by washing them at a temperature of 70°C.

Dry at room temperature.

7.1.3 Medicase® and antistatic Medicase® cover

Primary cleaning recommendation

- Wipe the cover with a cleaning and, if necessary, disinfecting cleaning agent
- Maximum chlorine content 2,000 ppm, in occasional use max. 5,000 ppm, ethanol solutions max. 60-80% (pH≈10)
- Avoid corrosive agents
- When using corrosive agents, rinse by wiping with clean water and then dry

Machine wash

- Open the zipper and turn the covers so that the textile sides are facing out
- Heat disinfecting recommendation 10min at 70°C
- Washing temperature 95°C
- Hang to dry (or use 1-point tumble dry in a washing bag)
- Do not chlorine bleach
- Do not iron
- Do not dry wash
- Do not use conditioners

Ensure that the cover is entirely dry before commissioning it.

7.1.4 Comfort add-on for the cover

- Open the add-on zipper and remove the add-on for washing. Put the add-on in a washing bag.
- Washing temperature 60°C
- Hang to dry
- Do not chlorine bleach
- Do not tumble dry
- Do not iron
- Do not dry wash
- Do not use conditioners

Ensure that the cover is entirely dry before commissioning it.

7.1.5 Rehab add-on for the cover

Remove the integrated foam support from the cover. After washing and drying the cover, the support can be placed back in their compartments. Close the zippers.

Do not wash the side supports made of foam plastic.

7.2 Checking the operability of the mattress system

To maintain the operational reliability of the mattress system, you need to monitor its condition throughout its lifetime as follows.

7.2.1 Controller

The condition of the controller must be checked as follows:

- When commissioning the controller
- When moving the controller
- When cleaning
- Whenever there is reason to believe the device has had an accident

The controller should be visually inspected for the condition of the power cable and the air tube connections, and that the seals of the plastic parts and the body between the operator panel/frame and the connection port/base are in place. In addition, any surface damage to the operating panel and the body, the hanger mounting of the controller, and the readability of technical type plate markings should be checked.

If you notice any damaged components, contact Carital® service.

7.2.2 Cover

The condition of the cover must be checked as follows:

- When cleaning
- If you suspect that the cover is broken or the interior is contaminated
- When the patient using the mattress system changes or weekly in long-term care

Check the cover's seams, zipper operation, condition of the surface of the cover and any darkening or stains on the interior of the cover and the potential foam side supports. Open the zipper of power cable conduit entirely to check the condition of the cable.

If you notice any damages, contact Carital® service.

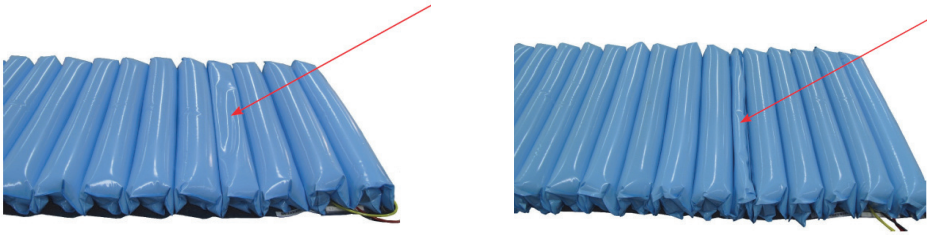
7.2.3 Cells

The condition of cells must be inspected:

- When cleaning
- If you suspect that the cover is broken or the interior is contaminated
- When the patient using the mattress system changes or weekly in long-term care

Strip the cover from the cells and check the overall condition of the cells visually (stretches, deterioration, thinning) and any punctured cells.

Punctured or broken upper cells can be identified visually by comparing them with other cells: a broken cells appears visibly emptier. The simplest way to identify a broken upper cell is to test by hand whether any of the cells feel significantly emptier compared with each other. Note that the mattress must be inflated in order to check the condition of upper cells.



Examples of punctured upper cells.

Leaks in the inner cells can be detected by the information signal displayed while the controller is used (see 6.3). In the event of a leak in the inner cells, the controller will not achieve the desired pressure values and the information signal is displayed automatically. Leaks can be detected visually by looking for cell sections that appear emptier than the rest of the inflated mattress and by feeling the inflation level of the section's cells by hand.

Example of an deflated middle cell section.

The controller is only able to detect defective inner cells according to chapter 6.3. The defective upper cells must be identified by the user according to the instructions stated in chapter 7.2.3.

If you notice any damaged cells or cell components, contact Carital® service.

7.2.4 Life cycle of the mattress system

The estimated life cycle of the mattress system, when properly cleaned and maintained under its normal intended purpose, has been assessed to be as follows:

- Controller and hanger: eight (8) years
- Cells and tube system: six (6) years
- Covers: five (5) years

If the mattress system is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the mattress system is used by a prominently sweating or mobile patient, the estimated life cycle of the cover and the cells may be shortened.

7.3 Scheduled maintenance

7.3.1 Scheduled maintenance interval

Scheduled maintenance must be performed on the mattress system's controller every three (3) years. Scheduled maintenance includes the technical inspection of the controller and the replacement of wearing parts.

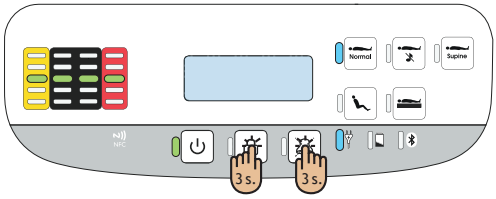
The controller will alert you to the need of scheduled maintenance one month before the deadline for the scheduled maintenance is reached.

See your Carital® service contact information on the last page of this user's guide.

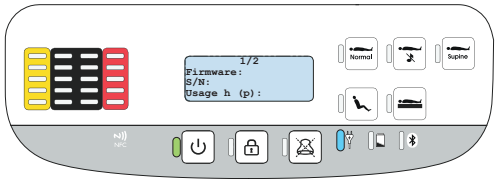
Scheduled maintenance may only be carried out by Carital® service.

7.3.2 Checking the maintenance data in the controller's maintenance view

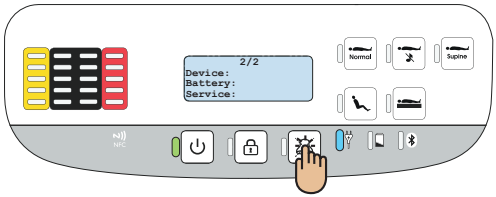
With the device running, press and hold down the lock and information signal reset button for three (3) seconds to access the maintenance view.



In the view, you can check the device software version, (*Firmware*), serial number (*S/N*), pump operation hours (*Usage h (p)*), date of device commissioning (*Device*), date of battery commissioning (*Battery*) and the date of the following scheduled maintenance (*Service*).

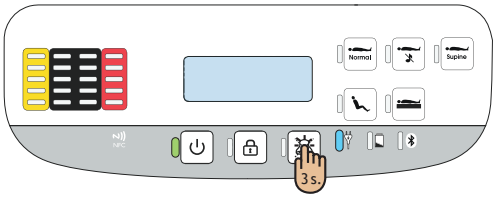


To change from one tab to another in the maintenance view, press the information signal reset button.



To return from the maintenance view to the normal operating mode, press and hold down the information signal reset button for three (3) seconds.

After returning from the maintenance view, the device checks the pressure values of the mattress system.

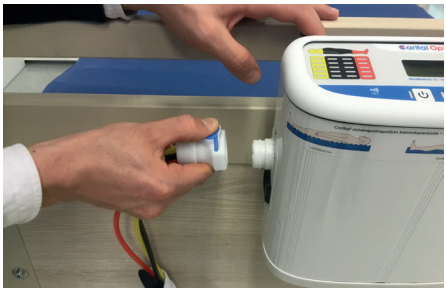


7.4 Storage and transport

Decommissioning the mattress system

1. *Press the standby button to stop the device operation and then disconnect the device's power plug from the mains.*

2. *Disconnect the power cable by pressing the yellow button and pulling the cable out.*



3. *Disconnect the air tube system's Sixtube connector by pressing the blue CPC button and pulling the connector out.*

The cells and the cover can be emptied for transport or storage by removing the air tubes from the controller and allowing the cells to deflate by themselves. You can expedite the deflation by carefully folding the cells inward.

Storage and transport conditions for the mattress system

Temperature	-25°C to +50°C > +35°C to +70°C with vapour pressure 50 hPa
Air humidity	max. 90%

- Store in a clean and dry place.
- The cells and the cover can be rolled up for storage using, for example, the transport bag (accessory)
- Alternatively, the cells and the cover can be hung on a bar with the bottom facing down, folded once with the bottom parts against each other or spread out flat.
- Do not store anything on top of the mattress system.
- Do not place sharp or heavy objects on or near the mattress system.
- Keep heat sources away from the mattress system.

To maintain battery performance, connect the controller to AC power continuously for 12 hours at least every three (3) months.

8 Disposal

Contaminated components must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.

8.1 Controller

The device must be decommissioned in accordance with waste electrical and electronic equipment regulations. The user's guide can be recycled with paper.

The device must be disposed of in accrdance with EU directive 2002/96/EC (WEEE Directive).

8.2 Cells and cover

The cells and cover can be disposed of as burnable matter or in mixed waste.

8.3 Packaging

The cardboard part of the mattress system packaging can be recycled with cardboard. The styrofoam packaging supports and packaging plastic can be recycled with plastic packaging.

9 Warranty

The Carital® Optima*Bario* mattress system has three-year warranty (36 months) from the date of purchase. The warranty covers all faults resulting from defects in materials or workmanship.

Repair will be carried free of charge at Carital® service on the basis of the warranty.

For warranty questions, please contact the mattress system's seller, always citing the device and subcomponent (controller/cells/cover) serial number or identifier.

The controller is intended for long-term use. However, it contains components that may break if the product is dropped or subjected to impact or vibration exceeding design standards. The limited manufacturer warranty does not apply to situations where the product has been mishandled.

10 Technical specifications

General description of medical device		
Essential performance of the medical device		Measures, adjusts and maintains the function-specific pressure values in the mattress system, specified in the software for each program.
Permissible weight of the patient		40-400 kg (cell width 90 cm) / 40-350 kg (cell width 85 cm)
Basic UDI-DI (GMN)		6429810591OPBDU
REF-code (total product)		OPBAE*ab6cddeeef* *a* = hanger type, *b* = tube set type, *c* = possible controller add-on, *dd* = cell type, *eee* = cover type, *f* = possible mattress system accessory
Controller		
REF code (controller)		OPBAE*a* *a* = hanger type
Dimensions (W x L x D)		26 x 26 x 11.5 cm
Weight		5 kg
Sound level		26.41 dB LAeq (24-hour operating time, 1 m)
Operating voltage		230V, 50HZ
Nominal input power		max. 35W
Battery type		Lithium-ion, 7.26V, capacity 2,650mAh, manufacturer: Cell-tech Oy / Varta Storage GmbH
Non-rechargeable battery type		CR2032, lithium-ion, 3.0V, capacity 230mAh, manufacturer: Varta Microbattery GmbH
Fuses		F1 & F2 - T 2.5A/250V 5X20 mm; F3 - T5A/250V 5X20 mm; F4 - T 2.0A/250V 5X20 mm; pump/motor fuse - T 1.6A/250V; main fuse: (voltage range E) - T315mA/250V 5X20 mm, breaking capacity (BC) 35A
Separating device		Power cable - BS546/C17, 1mm2, 10 A / 250 VAC; 50 Hz
Electromagnetic compatibility		See Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations - EMC
	**Applied part** **Applied part type**	Mattress (cover & cells) BF
IP22	**IP class**	IP22 (protected against particles with a diameter of 12.5mm or greater and from water falling vertically or at an angle not exceeding 15°)
	**Protection class**	II, insulated
	**Operating environment temperature range**	+10°C - +35°C
	**Operating environment air humidity %**	15% - 90%
	**Operating environment atmospheric pressure**	700 hPa - 1,060 hPa

Mattress & air tube system	
Dimensions (W x L x H)	85/90 x 200/210/220/230 x 13 cm, with Rehab add-on for the cover 90-120 x 200/210/220/230 x 13 cm
Weight	10-11 kg (depending on cell dimensions and potential mattress accessories)
Materials	**Cells:** TPU (cells, bottom mat & cell nipples); PBT (base adapters); POM (CPC adapters) **Air tube system:** TPU (air tubes); POM (CPC adapters) **Covers:** PU/PES (Medicase); PA/PU (Medicase AS) **Rehab-add-on for the cover:** PU/PES (cover); viscoelastic foam plastic - 50 kg/m^3 - 1,6 kPa CLD 40 % + support foam - 55 kg/m^3 - 6,5 kPa CLD 40 % (side bar composition) **Comfort add-on for the cover:** CO/PE
Flammability (mattress)	EN 597-1:2015; EN 597-2:2015; IMO 2010 FTP Code, Annex 1, Part 9
Applied legislation	
CE MD	Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR) (Rule 1 - Non-invasive devices / Rule 13 - All other active devices).
Design standards	
IEC 60601-1:2005 & IEC 60601-1:2005/AMD1:2012 except for clause 11.7 IEC 60601-2:2014 IEC 60601-1-6:2010 & IEC 60601-1-6:2010/AMD1:2013 IEC 60601-1-11:2015 IEC 62304:2006 & IEC 62304:2006/AMD1:2015 IEC 62366:2007 & IEC 62366:2007/AMD1:2014 IEC 60601-2-52:2009 subclause 201.9.101 EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 15223-1:2016 EN ISO 3758:2012 EN 597-1:2015 & EN 597-2:2015 EN 12182:2012 IMO 2010 FTP Code, Annex 1	

11 Contact details of the manufacturer, distributor and service

Manufactured by:

MediMattress Ltd.
Haukilahdenkatu 4
FI-00550 HELSINKI
tel. +358 306 40 40 40
info@medimattress.fi

Distributor and Service:

Australia

HospEquip Pty Ltd.
Canning Vale
Western Australia
6155
+61 (08) 9456 1661

Appendices

Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations – EMC

Electromagnetic Emissions (IEC 60601-1-2)			
Emission Test		**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11		Group 1, Class B	Carital mattress systems are suitable for use in all establishments including domestic establishments
Harmonic Emissions: IEC 61000-3-2		Complies	
Voltage fluctuations/flicker emissions: IEC 61000-3-3		Complies	
Electromagnetic Immunity (IEC 60601-1-2)			
Emission Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines, ±1kV for input/output lines	±2kV for power supply lines, ±1kV for input/output lines	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Surge 61000-4-5	±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±0.5 kV, ±1 kV, ±2 kV Line-to-ground	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the Carital mattress system requires continued operation during power mains interruption, it is recommended that the Carital controller is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: Ur is the A.C. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz), 6 Vrms in ISM bands between 150 kHz to 80 MHz (80 % AM at 1 kHz)		Portable and mobile RF communications equipment should not be used closer than 30cm (12 inch) of Carital controller, including cables. Using portable and mobile RF communications equipment too close may result Carital controller in not functioning properly. Interference may occur in the vicinity of equipment marked with the following symbol 
Radiated RF IEC 61000-4-3	10V/m (80 MHz to 2,7 GHz) and 20 V/m (800 MHz to 2,5 GHz)	10V/m (80 MHz to 2,7 GHz) and 20 V/m (800 MHz to 2,5 GHz)	
Proximity fields from RF wireless communications EQUIPMENT IEC 61000-4-3	9V/m 710MHz, 745MHz, 780MHz, 5,240MHz, 5,500MHz and 5,785MHz 27V/m 385MHz 28V/m 450MHz, 810MHz, 870MHz, 930MHz, 1,720MHz, 1,845MHz, 1,970MHz and 2,450MHz	9V/m 710MHz, 745MHz, 780MHz, 5,240MHz, 5,500MHz and 5,785MHz 27V/m 385MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	